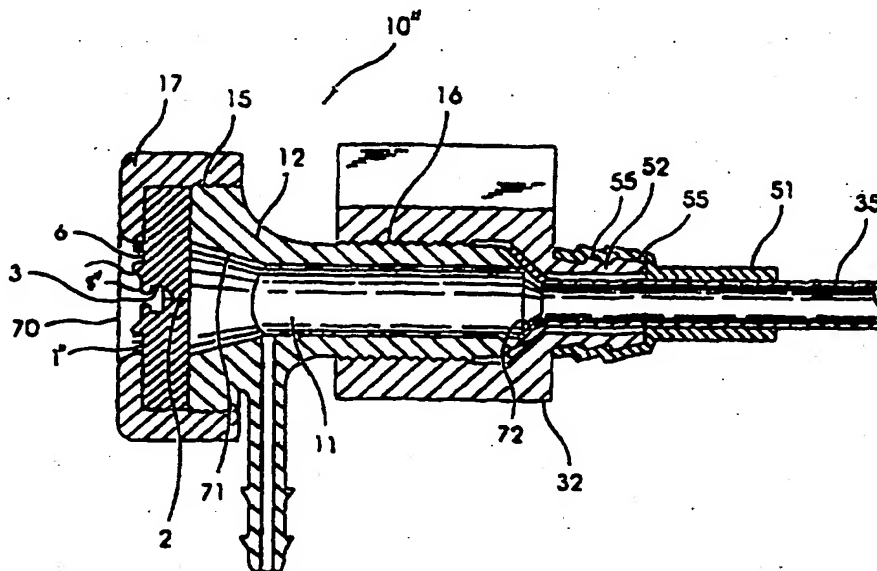


PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 5/00, 5/178		A1	(11) International Publication Number: WO 97/15338
			(43) International Publication Date: 1 May 1997 (01.05.97)
(21) International Application Number: PCT/US96/17076		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) International Filing Date: 24 October 1996 (24.10.96)			
(30) Priority Data: 08/547,441 24 October 1995 (24.10.95) US 08/547,500 24 October 1995 (24.10.95) US		Published <i>With international search report.</i>	
(71)(72) Applicants and Inventors: OSBORNE, Thomas, A. [US/US]; 2418 Spicewood Lane, Bloomington, IN 47401 (US). PAUL, Ram, H. [US/US]; 433 Park Square Drive, Bloomington, IN 47403 (US).			
(74) Agents: SISSELMAN, Kerry, P. et al.; Woodard, Emhardt, Naughton, Moriarty & McNett, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, IN 46204 (US).			

(54) Title: HEMOSTASIS CANNULA



(57) Abstract

This invention is a hemostasis cannula comprising a housing (10) having a passage (11) therethrough sized to receive a catheter (57), and a valve body (1, 1', 1'') mounted in the passage (11). The valve body (1, 1', 1'') includes an opening (2, 3, 102, 103, 112, 113, 2', 3', 2'', 3'') therethrough which forms a seal around a catheter (57) enclosed within the cannula. In one embodiment, an internal ring (8'') of pliable material lines at least a portion of the interior of the opening (2'', 3''). The valve body (1, 1', 1'') is compressed within the cannula housing (10). When the catheter (57) is removed, the valve body (1, 1', 1'') closes thus blocking airflow into the patient's blood vessel and also blocking blood flow out of the patient's blood vessel. The cannula housing (10) also includes a side port (45) for introducing fluids into the patient's blood vessel.

BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

HEMOSTASIS CANNULA

BACKGROUND OF THE INVENTION

This invention relates to a cannula or sheath and particularly to a cannula useful with angiographic catheters.

5 In certain angiographic studies, the angiographer uses the Desilets-Hoffman procedure to do a multiple study. In this procedure, the angiographer obtains access to a patient's blood vessel by inserting a hollow needle through the skin and into the lumen of the blood vessel. A guide wire is passed through the needle and advanced through the artery or vein into the organ to be studied. The needle is removed leaving the guide wire in the organ. A cannula and dilator are advanced over the wire into the vessel and the dilator is removed along the guide wire. The angiographer then conducts the multiple studies by inserting various types of catheters into the vessel through the cannula or sheath. In order to avoid excessive bleeding and to insure against the possibility of an air embolism, this technique requires occlusion of the passage through the cannula during catheter changes.

One method of obtaining the required occlusion is to position a valve body formed from a pliable material in the passageway of the cannula. Such valve bodies are shown for instance in U.S. Patent No. 4,000,739 to Stevens, U.S. Patent No. 4,430,081 to Timmermans, U.S. Patent No. 4,610,665 to Matsumoto et al., U.S. Patent No. 5,006,113 to Fischer and International Publication Number WO 91/10459 to Savage et al. In each of these patents, one or more

-2-

disk-like gaskets are mounted in the cannula passage. The disk-like gaskets or valve bodies include an opening therethrough which is biased to a closed position when no catheter is present in order to prevent an air embolism from occurring by air being drawn into the patient's vein through the cannula. When a catheter is inserted through the valve body into the passage of the cannula, the valve body conforms to the shape of the outer wall of the catheter, thereby preventing blood flow out of the cannula between the catheter and the valve body.

-3-

SUMMARY OF THE INVENTION

One embodiment of the present invention might include a hemostasis cannula comprising a housing having a passage sized to receive a catheter therethrough. A valve body, similar to the valve bodies described above, formed from a single piece of pliable material is mounted in the passage of the housing. The valve body includes a slit through one planar face which extends partly through the valve body and an opening through the opposing planar face extending only partly through the valve body. An internal ring is formed integrally as a portion of the hole, proximal to the external raised ring and to the face including the opening, and is likewise centered within the external ring. Both the slit and the opening extend far enough into the valve body that they intersect within the valve body. Also included is a means which contacts a portion of the peripheral edge of the valve body for compressing the valve body in a direction substantially perpendicular to the slit in order to maintain the slit in a fluid-tight seal. Optionally, an external raised ring which surrounds the opening may be provided.

One object of the present invention is to provide an improved hemostasis cannula.

Another object of the present invention is to provide a method for making an improved hemostasis cannula.

Related objects and advantages of the present invention will be apparent from the following description.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional view taken axially of a hemostasis cannula of one embodiment of the present invention.

5 FIG. 2 is an exploded partially cut-away view of the embodiment of FIG. 1.

FIG. 3 is a side elevational view of the cannula having a dilator unit and wire guide therein.

10 FIG. 4 is a view similar to FIG. 3 showing the cannula in position in the lumen of a blood vessel with a catheter enclosed therein.

FIG. 5 is a front view of the valve body used in the hemostasis cannula of FIGS. 1 and 2.

15 FIG. 6 is a bottom partially cut-away view of the valve body shown in FIG. 5.

FIG. 7 is a side view of the valve body shown in FIGS. 5 and 6.

20 FIG. 8 is a view looking axially into the recess portion of the housing of the hemostasis cannula of the present invention showing a front view of the valve body of FIGS. 5-7 before and after it has been compressed and fitted into the recess of the housing.

FIG. 9 is a front view of another valve body according to the present invention.

25 FIG. 10 is a front view of the valve body shown in FIG. 9 after being compressed.

FIG. 11 is a front view of still another valve body according to the present invention.

30 FIG. 12 is a front view of the valve body shown in FIG. 11 after being compressed.

FIG. 13 is a front view of a further embodiment of a valve body used in the hemostasis cannula of FIGS. 1 and 2.

FIG. 14 is a bottom partially cut-away view of the valve body shown in FIG. 13.

-6-

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring now more particularly to the drawings, there is illustrated in FIGS. 1 and 2 a hemostasis cannula which includes a housing 10 having a passage 11 therethrough adapted to receive a catheter. Housing 10 is made up of a member 12 having two externally threaded surfaces 15 and 16. A cap 17, which includes recess 18, is threaded down on the member 12 on the threads 15 and is glued in place by a suitable cement or the like. Valve body 1 is received into recess 18 and is sandwiched between cap 17 in member 12. As can be seen in FIGS. 1 and 2, the face 6 including the cylindrical recess or hole 3 of valve body 1 is directed towards the opening 70 of the cap 17.

The cannula housing 10 also includes an internally threaded member 32, the threads of which are suitable for mating engagement with the threads 16 on the member 12. The function of the member 32 is to receive and fix or hold the flexible tubing 35 to the housing 10. In the assembly procedure, adhesive or cement is placed on the flexible tubing 35 and between the members 12 and 32 for affixing the tubing and members together. The flexible tubing 35 has a flared end 36 which is fixed between the tapered surfaces 37 and 40 of the members 12 and 32.

-5-

FIG. 15 is a side view of the valve body shown in FIGS. 13 and 14.

FIG. 15A is an enlarged view of a portion of the valve body shown in FIGS. 13 - 15.

5 FIG. 16 is a cross-sectional view taken axially of a hemostasis cannula of another embodiment of the present invention.

FIG. 17 is a front view of a further embodiment of a valve body used in the hemostasis cannula of FIGS. 1 and 2,
10 as shown in FIG. 16.

FIG. 18 is a bottom partially cut-away view of the valve body shown in FIG. 17.

FIG. 19 is a side view of the valve body shown in FIGS. 17 and 18.

15 FIG. 19A is an enlarged view of a portion of the valve body shown in FIGS. 17 - 19.

-7-

Housing 10 is provided with a port 45 which communicates with passage 11 between valve body 1 and flexible tube 35 for introducing fluids into the patient's blood vessel. In order to ensure that blood does not flow out the flushing port 45, the physician normally maintains a positive pressure of flushing fluid through the flexible tubing 46 (FIGS. 3 and 4), which is attached to the projection 47 by means of the annular ridges 50. The flexible tubing 35 is further secured to housing 10 by means of shrinkable tubing 51 which is secured about collar 52 via the annular ridges 55. As seen in FIG. 3, a hollow plastic dilator 56 having an outer diameter substantially equal to that of catheter 57 (FIG. 4) may be positioned in the passage 11 with the tapered end 60 of the dilator extending past the distal end of tube 35. After the cannula has been inserted into the blood vessel over the guide wire 61 and the dilator 60, the dilator and guide wire may be removed and discarded.

Valve body 1 is oblong in shape and has a height dimension H_2 which is greater than the height dimension H_1 of recess 18. Therefore, valve body 1 must be compressed in the direction of arrows 8 in order to be received within recess 18. Valve body 1 includes a pair of opposing faces 6 which are separated by a peripheral edge 5. A hole or cylindrical recess 3 is made through one of the faces and extends partially through the valve body as shown in FIG. 1. The hole 3 may be formed by molding during the process of forming the disk or punched, cut or drilled in a separate operation. A slit 2 is made through the other face and extends partially through the valve body intersecting hole 3 within the valve body.

Valve body 1 is preferably made from silicon rubber or another elastomer having a Durometer hardness anywhere between 20 and 90. Referring to FIGS. 5-8, valve body 1 preferably has an oblong shape such that peripheral edge 5 includes a pair of parallel planar surfaces 4 which are

-8-

perpendicular to the plane defined by slit 2. Slit 2 preferably extends completely across one of the faces 6 and extends into the valve body to a depth of between 1/3 and 2/3 the thickness of the valve body. Hole 3 preferably has a diameter between 0.010 and 0.035 inches and, like slit 2, has a depth preferably between 1/3 and 2/3 the thickness of valve body 1. In any event, the combined depth of hole 3 and slit 2 must be sufficient that they intersect within the valve body and create an opening completely through the valve body for receiving a catheter or the like therethrough.

Of course, the oblong shape of valve body 1 results in it having a height dimension H_2 which is greater than its width dimension W_2 . FIG. 8 shows the valve body 1 both before and after it has been compressed in order to be positioned in recess 18 of housing 10. Before being compressed, valve body 1 has a height dimension H_2 which is greater than height dimension H_1 of recess 18 as shown in FIG. 2. So that the compression forces on valve body 1 are directed only perpendicularly to slit 2, valve body 1 has a width dimension W_2 which is less than the width dimension W_1 of recess 18. The oblong shape of valve body 1, when assembled into the cannula, applies a slight amount of pressure perpendicular to the slit making certain it closes completely after the removal of the dilator or a catheter. Planar portions 4 allow valve body 1 to expand in its width dimension without interacting with the recess when it is compressed and received within the recess 18.

FIGS. 9 and 10 show another embodiment of a valve body 101 which can be used with the hemostasis cannula of FIGS. 1 and 2. In this case, valve body 101 is oblong in shape and includes a pair of intersecting slits 102 and 103. The slit configuration of the valve body 101 may be as is more completely described in U.S. Patent No. 4,610,665 to Matsumoto et al., which description is incorporated herein by reference. Alternatively, the intersecting slits 102 and

-9-

103 may extend completely across the respective faces of valve 101, as is shown in FIGS. 9 and 10 . The important aspect in this case is that the oblong shape of valve body 101 is compressed along arrows 8 perpendicular to slit 102 so that the valve body may be received within the recess of a cannula housing as described previously. The compression force 8 improves the performance by insuring that slit 102 remains closed during catheter exchanges.

FIGS. 11 and 12 illustrate still another embodiment of a valve body according to the present invention. In this case, valve body 111 is oblong in shape similar to the shape discussed in reference to valve body 1 shown in FIGS. 5-8. In this case, however, valve body 111 includes a hole 112 completely through the valve body. Hole 112 includes boundary walls 113 and 114 which remain separate when valve body 11 is uncompressed. When sufficient compression is applied to valve body 111, as shown in FIG. 12, boundary walls 113 and 114 are forced together, thus forming a fluid-tight seal through the valve body. Thus, the compression concept of the present invention has application in hemostasis cannulas having two or more valve body gaskets as shown in U.S. Patent No. 4,000,739 to Stevens or U.S. Patent No. 4,430,081 to Timmermans, or to hemostasis cannulas containing a single valve body gasket as shown in U.S. Patent No. 4,610,665 to Matsumoto et al., and U.S. Patent No. 5,006,113 to Fischer.

FIGS. 13-15A show yet another embodiment of a valve body according to the present invention. FIG. 13 is a front view of a valve body 1' which is substantially similar to the valve body 1, with the major difference being the addition of a raised ring or doughnut 7' which surrounds the hole 3'. The valve body 1' may be substituted for the valve body 1 in the hemostasis cannula of FIGS. 1 and 2. Likewise, the face 6' including the cylindrical recess or hole 3' and the

-10-

raised ring 7' of valve body 1' may be directed towards the opening 70 of the cap 17 (FIGS. 1 and 2).

As with valve body 1, valve body 1' is oblong in shape and has a height dimension H_2 ' which is greater than the height dimension H_1 of recess 18 of FIG. 1. Therefore, valve body 1' must additionally be compressed in the direction of arrows 8 in order to be received within recess 18. Valve body 1' includes a pair of opposing planar faces 6' which are separated by a peripheral edge 5'. A hole or cylindrical recess 3' is made through one of the faces and extends partially through the valve body as shown in FIG. 14. The hole 3' may be formed by molding during the process of forming the disk or punched, cut or drilled in a separate operation. A slit 2' is made through the other face and extends partially through the valve body intersecting hole 3' within the valve body. Additionally, a raised ring 7' on the top surface of the valve provides a lead-in to the hole 3' of the valve body 1'. As such, the raised ring 7' makes it easier to place very small diameter devices through the valve. The extra material around the hole 3' additionally makes the valve less likely to tear.

Further, valve body 1' (including raised ring 7') is preferably made from silicon rubber or another elastomer having a Durometer hardness anywhere between 20 and 90. Referring now to FIGS. 13-15A, valve body 1' preferably has an oblong shape such that peripheral edge 5' includes a pair of parallel planar surfaces 4' which are perpendicular to the plane defined by slit 2'. Slit 2' preferably extends completely across one of the faces 6' and extends into the valve body to a depth of between $1/3$ and $2/3$ the thickness of the valve body.

In one particular embodiment of the present invention, the thickness of the valve body 1' may be .062 inches +/- .002 inches and the slit depth may be between .040 and .045 inches. Hole 3' preferably has a diameter of between 0.010

-11-

and 0.035 inches and, like slit 2', has a depth preferably between $1/3$ and $2/3$ the thickness of valve body 1'. In any event, the combined depth of hole 3' and slit 2' must be sufficient that they intersect within the valve body and
5 create an opening completely through the valve body for receiving a catheter or the like therethrough. Of course, the oblong shape of valve body 1' results in it having a height dimension H_2' which is greater than its width dimension W_2' , to provide a better closing force on the
10 slit. For example in the above mentioned particular embodiment of the present valve, height H_2' is between .405 and .410 inches in diameter compared to a width W_2' of between .340 and .360 inches.

The raised ring 7' is centered around the hole 3'.
15 Additionally, as can be seen more clearly in FIG. 15A, the inner wall 9' of the raised ring 7' is sloped from the top of the raised ring 7' down to the face 6'. An angle θ can be measured between a plane parallel to the face 6' and the inner wall 9'. In the above mentioned particular embodiment
20 angle θ is 45° .

Further, in that embodiment, the outer diameter of raised ring 7' is chosen to be between .145 -.155 inches while the inner diameter, measured at the top of the raised ring, may be between .080 -.095 inches in diameter.
25 Additionally, the raised ring may extend between .025 and .030 inches above the face 6'.

As can be further seen in FIG. 15A, in the preferred embodiment, the tapered walls terminate at the surface of the planar face 6' prior to the beginning of the hole 3',
30 thus forming a small planar surface between the hole 3' and the raised ring 7'. Alternately, the sloping inner wall 9' can terminate directly at the edge of the hole 3'.

As with the previous embodiments of the invention, before being compressed, valve body 1' has a height
35 dimension H_2' which is greater than height dimension H_1

-12-

of recess 18 shown in FIGS. 1 and 2. So that the compression forces on valve body 1' are directed only perpendicularly to slit 2', valve body 1' has a width dimension W_2' which is less than the width dimension W_1' of recess 18 of FIG. 1. Planar portions 4' allow valve body 1' to expand in its width dimension without interacting with the recess when it is compressed and received within the recess 18 of FIG. 1.

FIGS. 16-19A show a further embodiment of a valve body according to the present invention. FIG. 16 is a cross-sectional view taken axially of a hemostasis cannula of another embodiment of the present invention. The hemostasis cannula of FIG. 16 is identical to that shown in FIGS. 1 and 2, with the exception being that the valve body 1" replaces valve body 1 of FIG 1. In FIG. 17 there is shown a front view of the valve body 1" which is substantially similar to the valve body 1', disclosed herein. As with the valve bodies 1 and 1', the face 6" of valve body 1" includes a recess or hole 3". The recess 3" may be a cylindrical recess as described above.

Further, as with valve body 1' the valve body 1" includes a raised ring 7", external to and surrounding the recess 3". The raised ring 7" may be directed towards the opening 70 of the cap 17 (FIG. 16) when assembled into the hemostasis cannula (10" of FIG. 16). One important difference between valve 1" and valve body 1' is the addition internal to valve body 1" of of an integrally molded internal ring or doughnut 8" (FIGS. 16 and 18-19A). Internal ring 8" is formed integrally around a portion of the internal perimeter of recess 3", distal from the portion of the recess intersected by the slit. Further a plane drawn through the internal ring 8", parallel to the face 6", would be perpendicular to a plane drawn through the slit 2". The internal ring 8" may be formed adjacent to and at the same level as the face 6" such that the external ring

-13-

height (ERH), measured to the internal ring face 8a", is equal to the total ring height (TRH), measured to the valve face 6". Alternatively, as shown in FIG. 19A, the internal ring face 8a" of internal ring 8" can be located at a level higher than the level of valve face 6" such that TRH is greater than ERH. Similarly, the ring may be located in the recess 3" such that the ring face 8a" is located at a level below that of the valve body face 6" (TRH less than ERH).

As with valve body 1', valve body 1" is oblong in shape and has a height dimension H_2 " which is greater than the height dimension H_1 of recess 18 of FIG. 2. Therefore, valve body 1" must additionally be compressed in the direction of arrows 8 in order to be received within recess 18. Again, the oblong shape of the disc and the compressive forces in the direction of arrows 8 have been found to enhance the closing force applied to the slit, as well as make the valve body insensitive to variations in slit height and hole depth. Likewise, valve body 1" of FIGS. 17-19A includes a pair of opposing planar faces 6" which are separated by a peripheral edge 5".

As noted above, a hole or cylindrical recess 3" is made through one of the faces 6" and extends partially through the valve body as shown in FIG. 18. The hole 3" may be formed by molding during the process of forming the disk or punched, cut or drilled in a separate operation. In one preferred embodiment, the hole 3" and the internal ring 8" are formed integrally using a pin which has been modified to form the cylindrical recess in the face 6" of the valve body 1". The modification is achieved by grinding a groove in the aforementioned pin. In one preferred embodiment, the pin groove was cut to have a radius of about .020 inches. Thus, the pin portion is used to form the recess 3", while the groove forms the internal ring 8". The internal ring 8" has been added to prevent leaking through the valve body 1" when small diameter devices (such as small diameter wire

-14-

guides, etc.) are used. The internal ring 8" offers an improvement over the valve body designs of valve bodies 1 and 1' when used with small diameter devices. For example, the internal ring 8" has been found to provide a better seal around guide wires in the range of .018" to .038". However, tests have shown an increase of sealing efficiency over valve bodies having a recess but no internal ring with all devices put through the valve.

As with the valve body 1', a slit 2" is made through the other face 6", opposite to the face 6" bearing the recess 3" therethrough. The slit 2" extends partially through the valve body 1" intersecting hole 3" within the valve body 1". Likewise, the raised ring 7" on the top surface of the valve provides a lead-in to the hole 3" of the valve body 1". As such, the raised ring 7" makes it easier to place very small diameter devices through the valve, while the internal ring 8" provides for a tighter seal around those devices. The extra material externally surrounding the hole 3" additionally makes the valve less likely to tear. The internal ring 8" additionally imparts some degree of tear propagation resistance for tears emanating from the slit.

Further, valve body 1" (including raised ring 7" and internal ring 8") is preferably made from silicon rubber or another elastomer having a Durometer hardness (Shore A scale) anywhere between 20A and 90A. Evaluations were conducted on valve bodies differing in Durometer (Shore A scale from 29A to 51A) and diameter. Other physical characteristics measured were weight and thickness. Insertion force measurements and leakage were then conducted on the valves after they were built up in cap and body assembly. The optimal scenario was determined to be where the insertion force (measured by the amount of force needed to insert a 8 Fr. dilator across the valve at a constant rate) is low, and the leakage nonexistent. An Analysis of Variance was conducted on the physical characteristics, and

-15-

it was found that the most statistically significant factor effecting the insertion force was Durometer. It was found that the higher the Shore A Scale number, the greater was the insertion force.

5 Experimentally, the Miles-Mobay 30 Durometer material exhibited the lowest insertion force measured. Although the 30 Durometer material seem to be the most preferred hardness for the present invention, Durometers in enhanced tear
10 resistant material from 25A to 50A would additionally make practical valves, such as valve bodies 1, 1' and 1".

Referring now to FIGS. 17-19A, valve body 1" preferably has an oblong shape such that peripheral edge 5" includes a pair of parallel planar surfaces 4" which are perpendicular to the plane defined by slit 2". Slit 2" preferably extends
15 completely across one of the faces 6" and extends into the valve body to a depth of between 1/3 and 2/3 the thickness of the valve body.

In one particular embodiment of the present invention, the thickness of the valve body 1" may be .062 inches +/-
20 .002 inches and the slit depth may be between .040 and .045 inches. Hole 3" preferably has a diameter of between 0.010 and 0.035 inches and, like slit 2", has a depth preferably between 1/3 and 2/3 the thickness of valve body 1". The combined depth of hole 3" and slit 2" must be sufficient
25 that they intersect within the valve body and create an opening completely through the valve body for receiving a catheter or the like therethrough. In one particular embodiment the overlap between the valve body and the slit was .007 inches. Of course, the oblong shape of valve body
30 1" results in it having a height dimension H_2 " which is greater than its width dimension W_2 ". In the above mentioned particular embodiment, height H_2 " is between .405 and .410 inches in diameter compared to a width W_2 " of between .340 and .360 inches.

35 In the present embodiment, the raised ring 7" is

-16-

centered around the hole 3". Additionally, as can be seen more clearly in FIG. 19A, the inner wall 9" of the raised ring 7" is sloped from the top of the raised ring 7" down to the face 8a" of the internal ring 8". An angle θ can be measured between a plane parallel to the face 8a" and the inner wall 9". In the above mentioned particular embodiment angle θ is 45°.

Further, for the purposes of example only, the dimensions of one particular valve body of the type described in connection with the embodiment of FIGS. 17-19A will be given. Note that these dimensions are given as example only and are not meant to limit the present invention only to valve bodies having those dimensions listed herebelow. In the one particular example described in this paragraph, the outer diameter of raised ring 7" was chosen to be between .145 - .155 inches, preferably .150 inches, while the inner diameter, measured at the top of the raised ring, may be between .080 - .095 inches in diameter. Additionally, the raised ring may extend between .025 and .030 inches above the face 6" (TRH = between .025 and .030 inches). In this particular example the height (ERH) from the top of the external ring 7" to the face of the internal ring 8a" is .016 inches. In this same particularly described example the internal ring height (IRH) was chosen to be .021 inches.

Further in this example, the internal diameter (I.D.) of the internal ring 8" in one embodiment is .016 inches before it is put in the cap and body. After being constrained by the cap and body (and resultingly compressed in the direction of arrows 8 in FIG. 2, perpendicular to the slit 2") the I.D. becomes oval and measures .013 inches by .017 inches due to the compressive effects of the cap on the oblong disc. Additionally in this particular example, the diameter of the recess 3" was chosen to be between .030 inches and .040 inches, more particularly the diameter was

-17-

chosen to be .036 inches. Additionally, the hole height (HH) measured from the base of the hole 3" to the proximal surface of the ring 8" is .016 inches in the particularly described embodiment. The hole width HW of the hole 3" in that particularly described example was .036 inches. Further, in the present example, the recess 3" and the slit 2" overlap by .007 inches.

As can be further seen in FIG. 19A, in the preferred embodiment, the tapered walls terminate at the surface of the internal ring face 8a" prior to the beginning of the hole 3", thus forming a small planar surface between the hole 3" and the raised ring 7". Alternately, the sloping inner wall 9" can terminate directly at the end of the ring face 8a", at the lead in to the hole 3".

As with the previous embodiments of the invention, before being compressed, valve body 1" has a height dimension H_2 " which is greater than height dimension H_1 of recess 18 shown in FIGS. 1 and 2. So that the compression forces on valve body 1" are directed only perpendicularly to slit 2", valve body 1" has a width dimension W_2 " which is less than the width dimension W_1 " of recess 18 of FIG. 1, which, as noted above, will provide a greater closing force to the slit when the valve is compressed in the cannula cap and body assembly. Planar portions 4" allow valve body 1" to expand in its width dimension without interacting with the recess when it is compressed and received within the recess 18 of FIG. 1.

The compression applied to the valve body could be produced by any of a number of methods. The recess in the housing could be shaped so that it applied the needed pressure to produce a closing force to the opening in the valve body. The closing force produced by the compression on the opening through the valve body improves the performance of most if not all of the valve bodies of the prior art as well as those in accordance with FIGS. 5 - 8,

-18-

13 - 15A and 17-19A. It has been found that valve bodies 1, 1' and 1" work well with a wide range of device diameters, and because of the compression, the valve body is insensitive to such factors as slit depth and hole diameter.

In operation as shown in FIG. 4, a hollow needle subcutaneously enters the blood vessel. When the lumen 62 of the vessel has been penetrated, guide wire 61 is threaded into the needle and blood vessel, and the needle is removed. A hollow plastic dilator 60 is then passed through passage 11 of the cannula housing and is slid over guide 61. The physician then dilates the hole through the vessel wall by maneuvering the tapered end 60 of the dilator 56, and introduces the entrance tube 35 into vessel lumen 62. It should be noted that the outer diameter of the dilator at its constant diameter portion is close to the outer diameter of the flexible tubing 35 so that tubing 35 is guided through the wall of the vessel by the dilator. The cannula is then taped into position on the body of the patient. With the feed tube 46 fastened to projection 47, and while maintaining a slow flow of heparin saline solution into passage 11 through the tube 46, the physician withdraws dilator 56 and guide 61. At this point, slit 2, 2' or 2" in valve body 1, 1' or 1", respectively, closes. The closure of slit 2, 2' or 2" insures that no air passes through the opening 70 of cap 17 and through valve body 1, 1' or 1" into passage 11. Thus, the present device not only prevents blood loss but also insures against the possibility of an air embolism.

The catheter 57 is then introduced through the opening in cap 17 and passes through valve body 1, 1' or 1". Catheter 57 is guided through passage 11 and flexible tubing 35 by the tapered surfaces 71 and 72. The catheter finally passes into lumen 62 of the blood vessel. Hole 3, 3' or 3" (and in the case of valve bodies 1' and 1", raised rings 7'

-19-

and 7" and further in the case of valve body 1", internal ring 8") forms a seal around the exterior wall of catheter 57 and prevents blood loss through hole 70 in the cap. Passage 11 is constantly flushed by a flow of heparin saline solution introduced through the port 45 and tubing 46 in order to prevent clotting. When catheter 57 has been maneuvered into position, radiopaque fluid is injected through the catheter and X-ray photographs may be taken of the radiopaque configuration of the organ being studied.

When multiple studies are indicated, or if a catheter has not been positioned correctly, the catheter may be easily removed from the cannula housing and replaced with another catheter. Also, a guide wire may be used by passing it through the cannula housing if needed. Because slit 2, 2' or 2" in valve body 1, 1' or 1" closes at the time of removal of the catheter, no bleeding is experienced by the patient and no air is allowed to enter into the patient's blood vessel in the event that the pressure external of the cannula is greater than the pressure within the blood vessel.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character. For example, the recess in the cannula housing can have various shapes so long as the valve body is of a corresponding cooperating shape to provide compression force in an appropriate direction tending to close the opening in the valve body. It is to be understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

-20-

WHAT IS CLAIMED IS:

1. A hemostasis cannula comprising:

a housing having a passage sized to receive a catheter having an outer wall and a blunt end;

5 a valve body formed from a single piece of pliable material and mounted in said passage of said housing, said valve body having a first planar face, a second planar face and a peripheral edge separating said faces, said first face including a slit extending entirely across said first planar face and defining a slit plane extending only partly through
10 said valve body, said second planar face including a recess partly through said valve body, said slit intersecting said recess within said valve body, said valve body further including an internal ring of pliable material mounted
15 within at least a portion of said recess;

means, contacting a portion of said peripheral edge, for compressing said valve body only in a direction substantially perpendicular to said slit plane to maintain a fluid tight seal through said valve body;

20 said valve body conforming to said outer wall of said catheter without cutting said pliable material when said blunt end of said catheter penetrates into said passage through said slit and said recess of said valve body thereby maintaining a fluid tight seal between said outer wall of
25 said catheter and said valve body;

said slit and said recess being formed in said valve body while unstressed before being mounted in said passage of said housing;

30 said second planar face including a raised ring of pliable material external to and surrounding said recess; and

said peripheral edge including a first planar edge and a second planar edge, said first and second planar edges being substantially perpendicular to said slit plane.

-21-

2. The hemostasis cannula of claim 1 wherein said recess is a cylindrical recess having a circular cross section.

3. The hemostasis cannula of claim 2 wherein said valve
5 body has a height dimension perpendicular to said slit plane;
said housing including a housing recess having a height
dimension across said housing recess less than said height
dimension of said valve body; and
whereby said valve body is compressed along a line
10 perpendicular to said slit plane when said valve body is
received within said housing recess.

4. The hemostasis cannula of claim 3 wherein said valve
body has a width dimension perpendicular to said height
dimension; and
15 said housing recess has a width dimension greater than
said width dimension of said valve body.

5. A hemostasis cannula comprising:
a housing having a passage sized to receive a catheter
having an outer wall and a blunt end;
20 a valve body formed from a single piece of pliable
material and mounted in said passage of said housing, said
valve body having a first planar face, a second planar face
and a peripheral edge separating said faces, said first face
including a slit defining a slit plane extending only partly
25 through said valve body, said second face including a recess
partly through said valve body, said slit intersecting said
recess within said valve body, said valve body further
including an internal ring of pliable material mounted
within at least a portion of said recess;
30 means, contacting a portion of said peripheral edge, for
compressing said valve body only in a direction

-22-

substantially perpendicular to said slit plane to maintain a fluid tight seal through said valve body;

said valve body conforming to said outer wall of said catheter without cutting said pliable material when said blunt end of said catheter penetrates into said passage through said slit and said recess of said valve body thereby maintaining a fluid tight seal between said outer wall of said catheter and said valve body; and

said slit and said recess being formed in said valve body while unstressed before being mounted in said passage of said housing.

6. The hemostasis cannula of claim 5 wherein said recess is a cylindrical recess having a circular cross section.

7. The hemostasis cannula of claim 6 wherein said valve body has a height dimension perpendicular to said slit plane;

said means for compressing includes a housing recess formed in said passage of said housing and having a height dimension across said recess less than said height dimension of said valve body; and

whereby said valve body is compressed along a line perpendicular to said slit plane when said valve body is received within said recess.

8. The hemostasis cannula of claim 7 wherein said valve body has a width dimension perpendicular to said height dimension; and

said housing recess having a width dimension greater than said width dimension of said valve body.

9. The hemostasis cannula of claim 8 wherein said valve body includes a raised ring of pliable material surrounding said recess.

-23-

10. The hemostasis cannula of claim 9 wherein said peripheral edge of said valve body includes a pair of substantially planar surfaces perpendicular to said slit plane, said width dimension of said valve body being the distance between said planar surfaces.

11. The hemostasis cannula of claim 10 wherein said slit extends completely across said first face.

12. A method for making a hemostasis cannula comprising the steps of:

- 10 providing a housing having proximal and distal ends, said housing including a recess and a passage sized to receive a catheter having an outer wall and a blunt end, said recess having a first height dimension and a first width dimension perpendicular to said first height dimension;
- 15 providing a valve body formed from a single piece of pliable material, said valve body having a first planar face, a second planar face and a peripheral edge separating said faces, said first planar face including a slit defining a slit plane extending only partly through said valve body,
- 20 said second planar face including a cylindrical recess partly through said valve body, said slit intersecting said cylindrical recess within said valve body, wherein said valve body additionally includes a second height dimension and a second width dimension perpendicular to said second
- 25 height dimension and to said slit plane, said second height dimension of said valve body being greater than said first height dimension of said recess and said second width dimension of said valve body being less than said first width dimension of said recess;
- 30 said valve body including an internal ring of pliable material mounted within at least a portion of said cylindrical recess;

-24-

said valve body further including an external ring or pliable material surrounding said cylindrical recess; and receiving said valve body within said recess with said second face directed towards said proximal end of said
5 cannula housing such that said valve body is compressed only in a direction substantially perpendicular to said slit plane when said valve body is received within said recess.

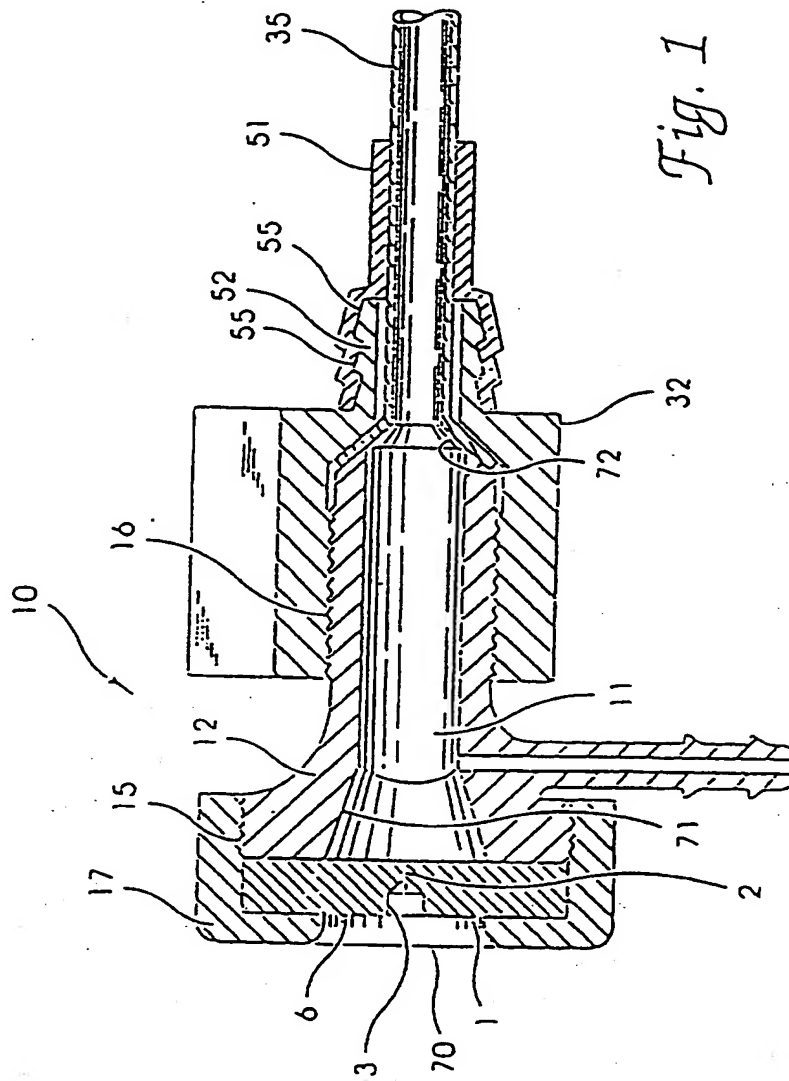


Fig. 1

2/10

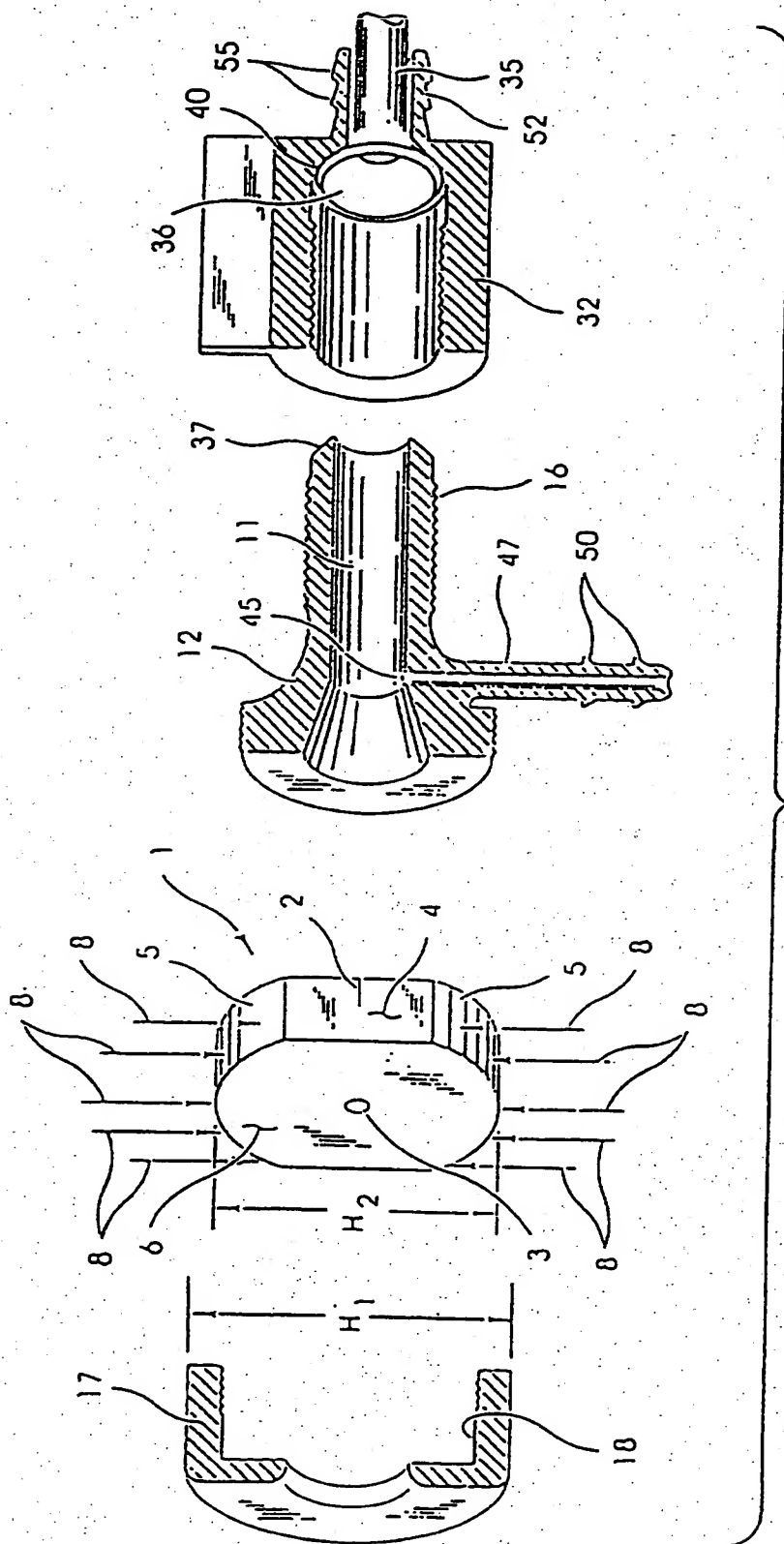


Fig. 2

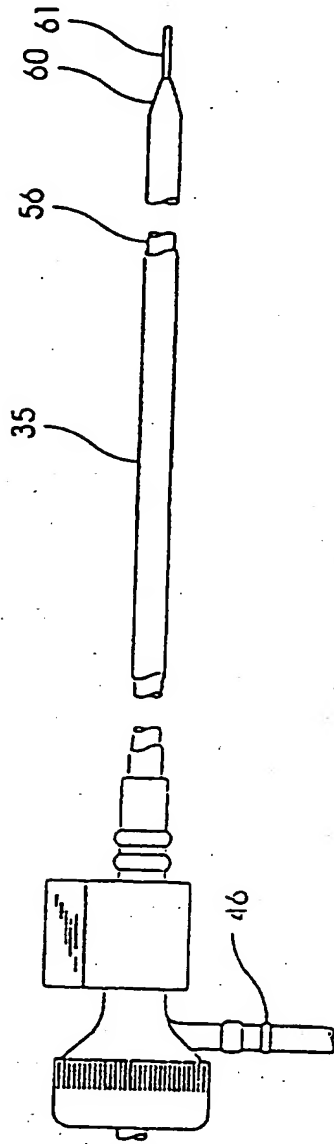


Fig. 3

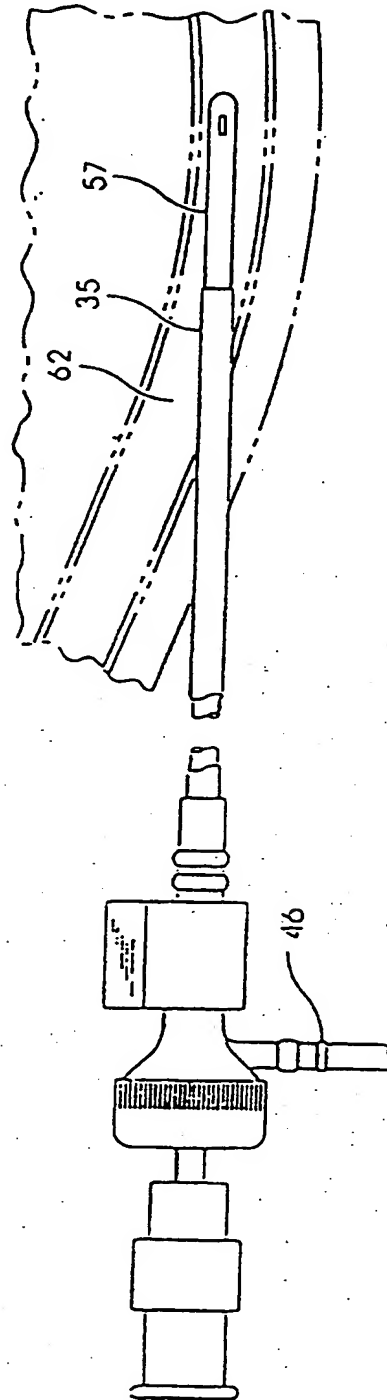


Fig. 4

Fig. 8

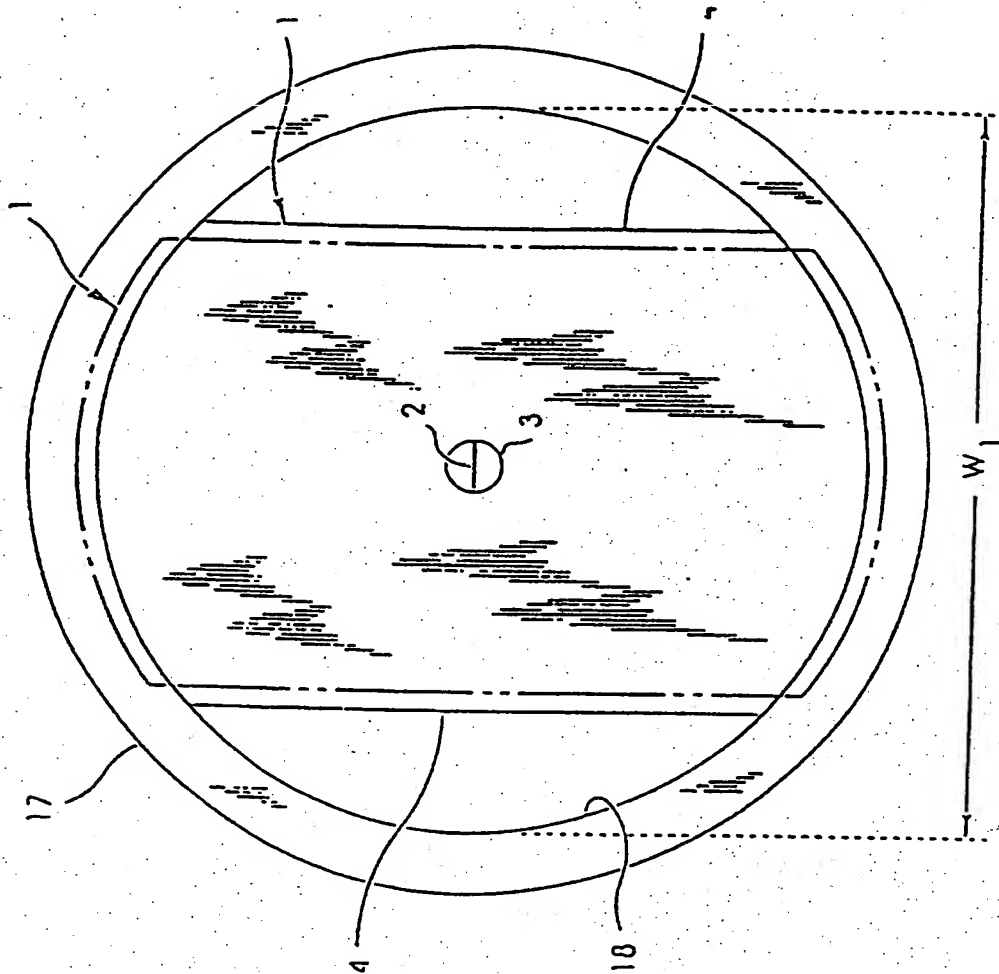


Fig. 7

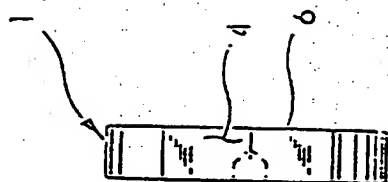


Fig. 5

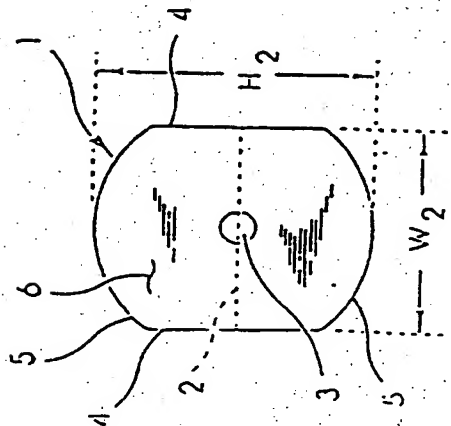
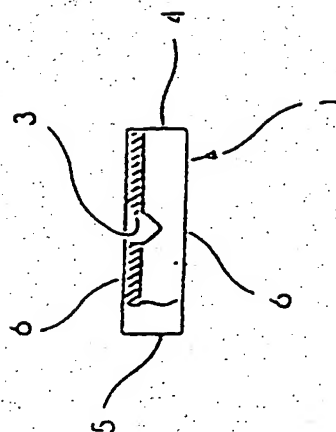


Fig. 6



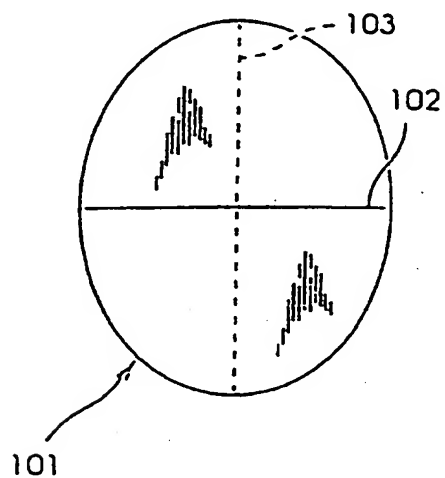


Fig. 9

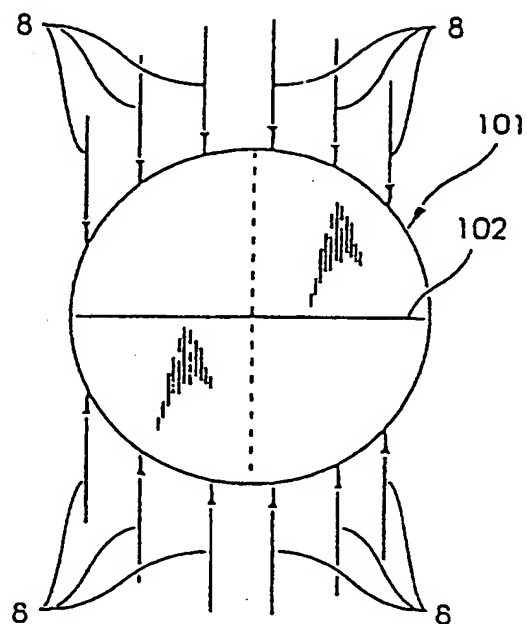


Fig. 10

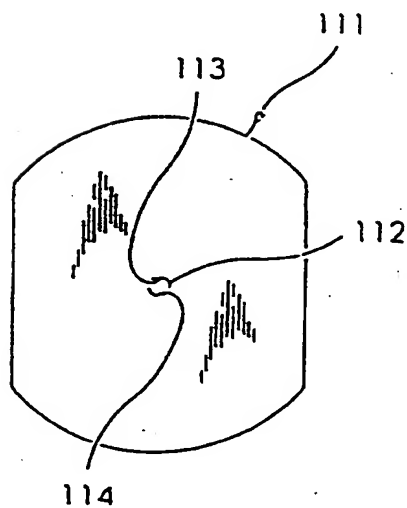


Fig. 11

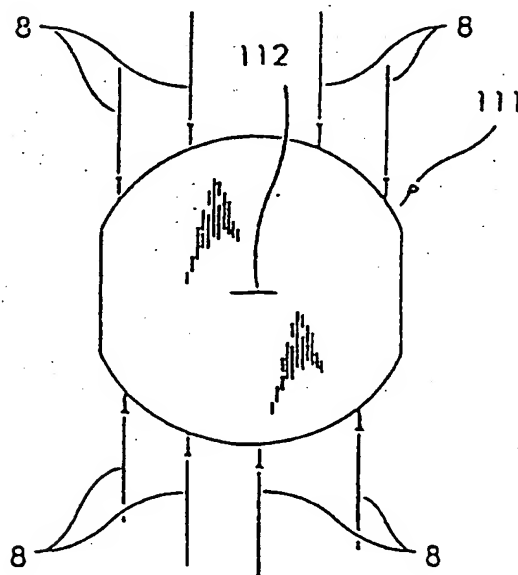


Fig. 12

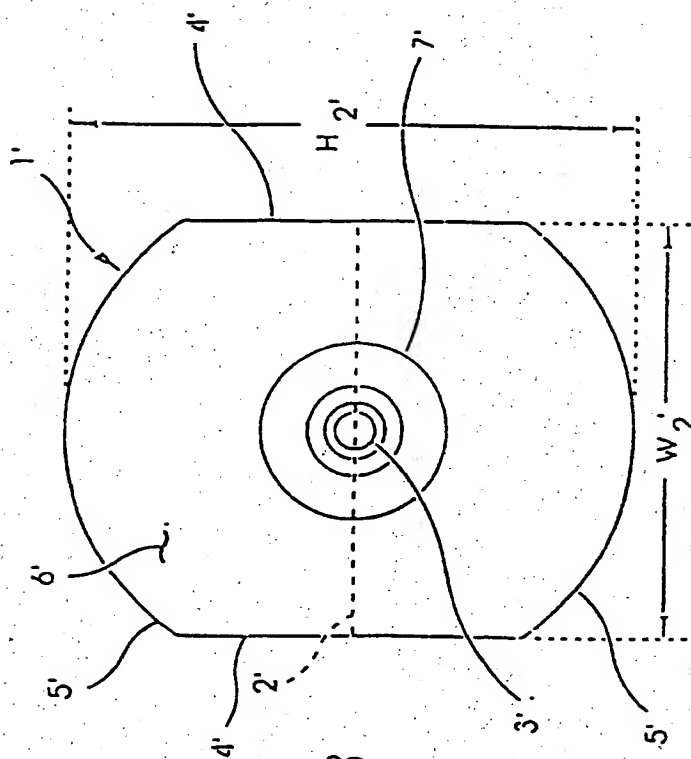


Fig. 13

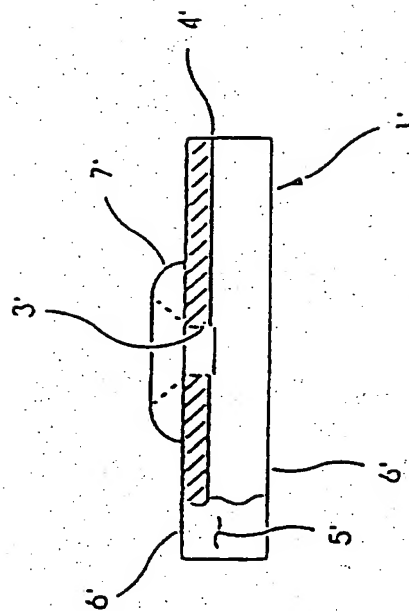


Fig. 14

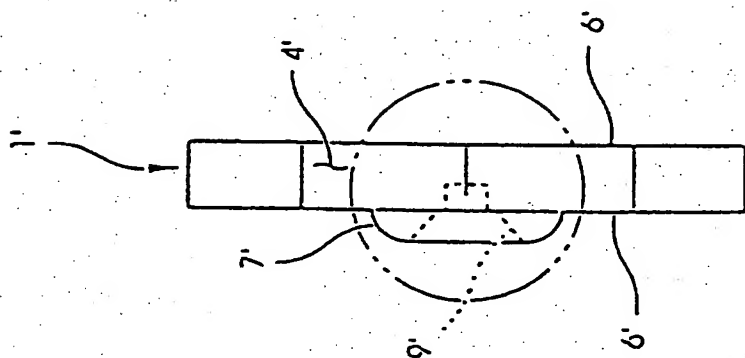


Fig. 15

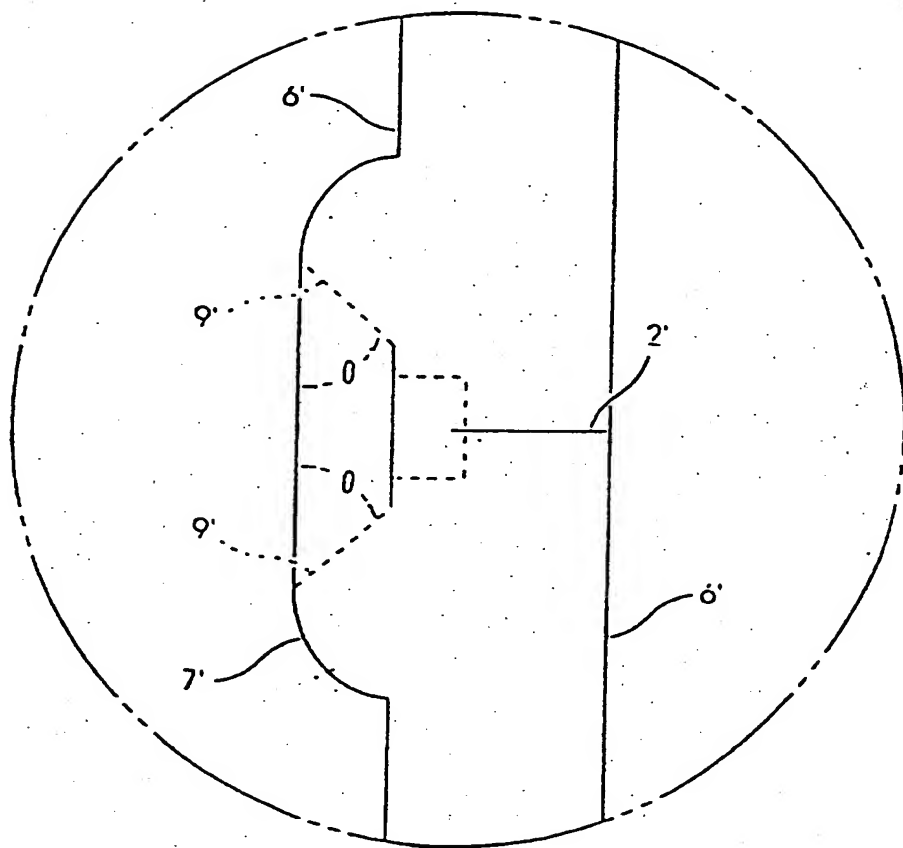


Fig. 15A

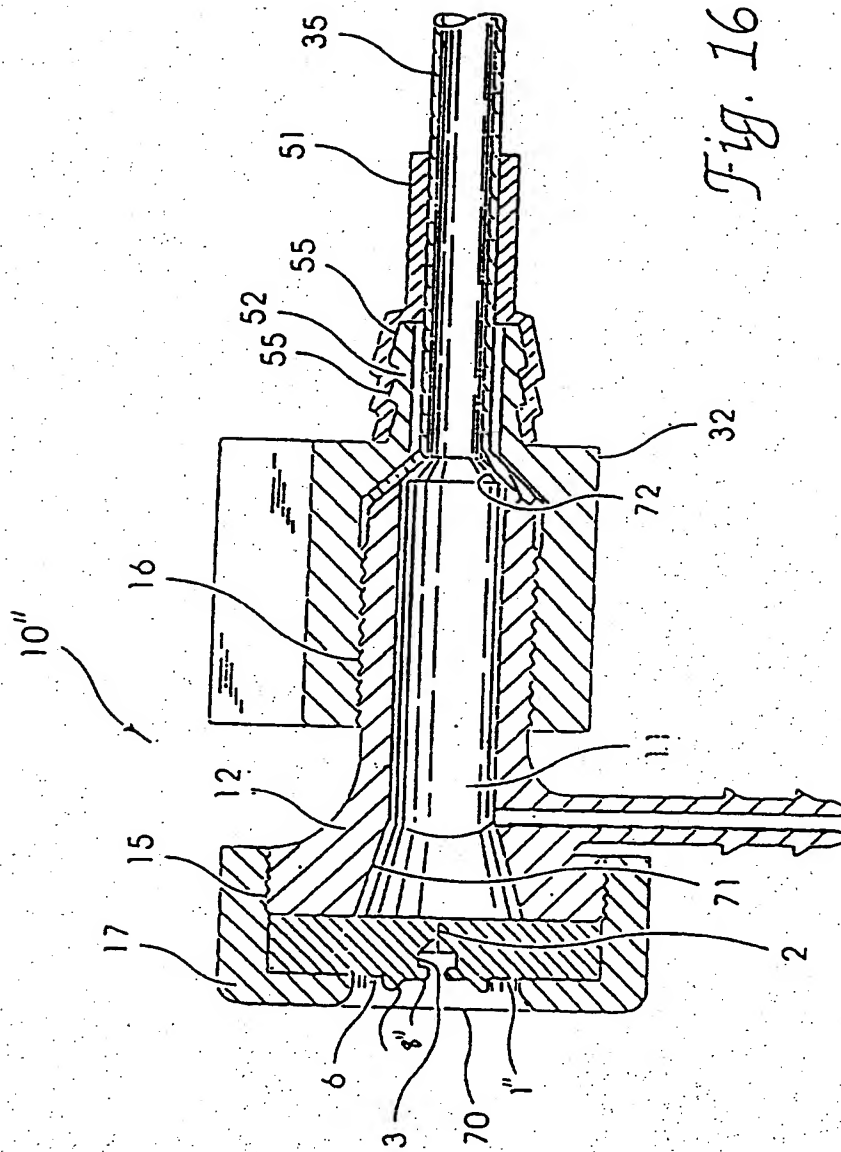


Fig. 16

9/10

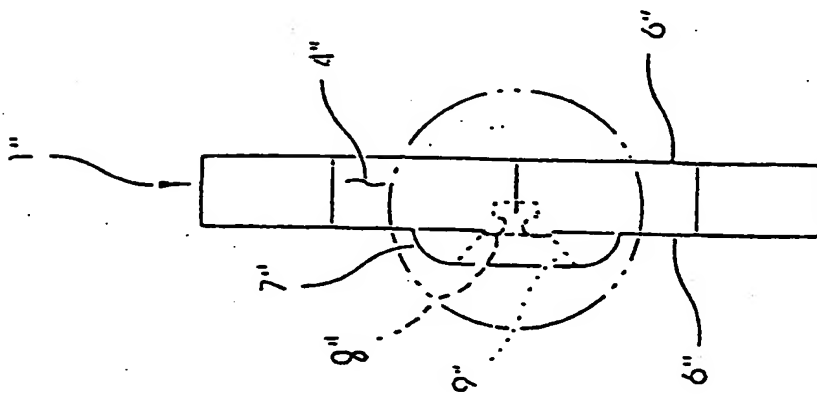


Fig. 19

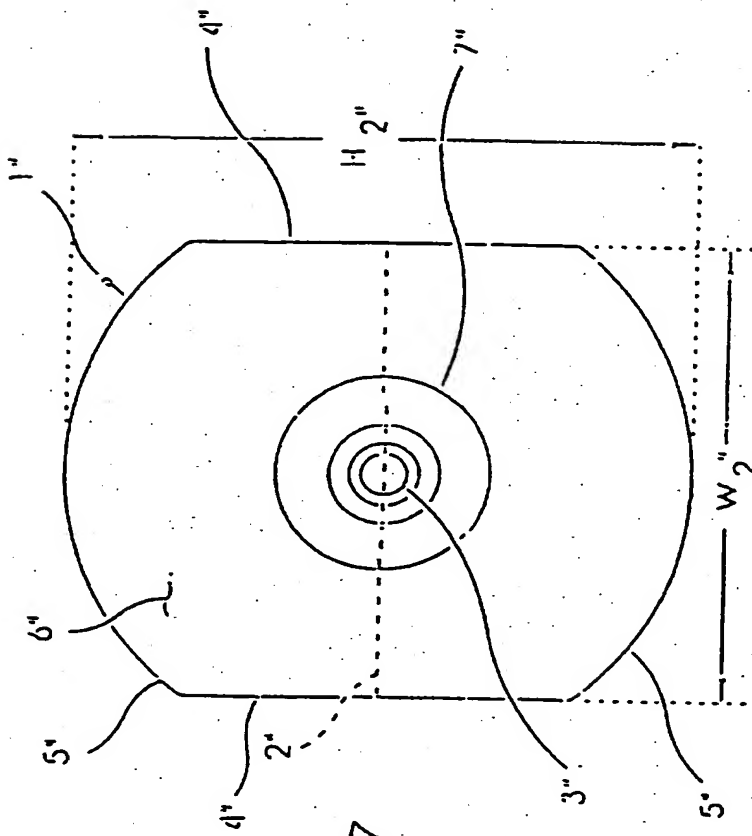


Fig. 17

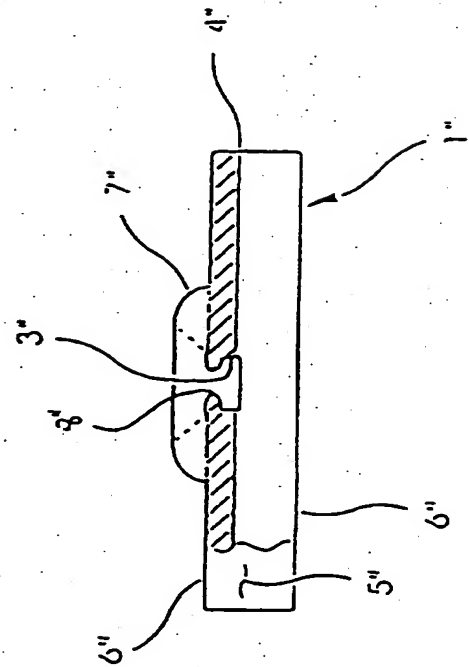
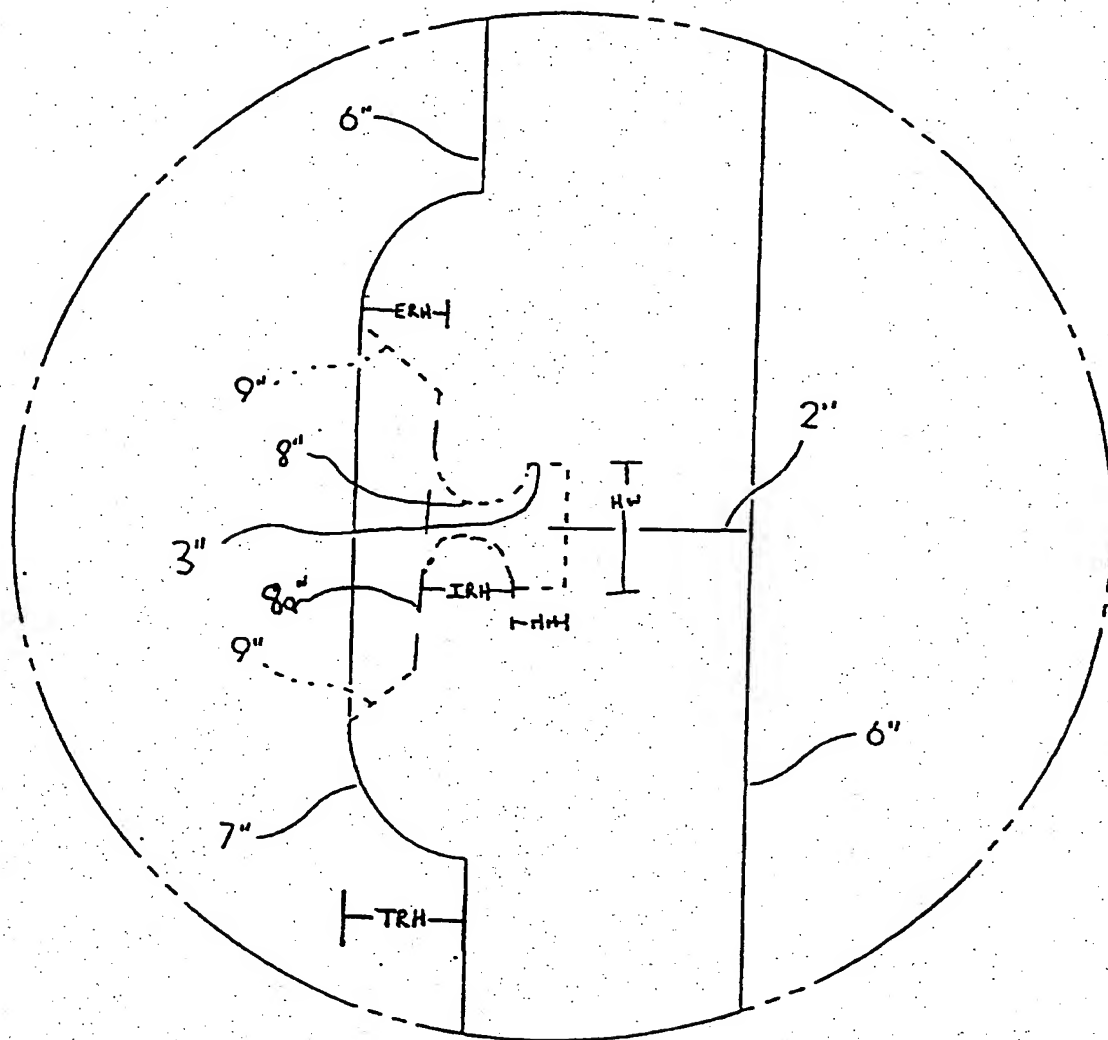


Fig. 18

*Fig. 19A*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/17076**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) : A61M 5/00, 178

US CL : 604/167, 256

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 251/149.1-149.3; 604/19, 30, 31, 104, 122, 158, 164, 167, 169, 174, 175, 180, 244, 255, 256, 260, 267, 372, 903

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,409,463 A (THOMAS et al) 25 April 1995, figures; col.4, line 49 to col.5, line 12; and claim 9.	1-12
Y	US 3,853,127 A (SPADEMAN) 10 December 1974, Fig. 70.	1-12
Y	US 4,809,679 A (SHIMONAKA et al) 07 March 1989, Fig. 5.	1-12
Y	US 5,006,113 (FISCHER) 09 April 1991, col. 3, lines 46-55.	1-5, 11

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	* T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
* A document defining the general state of the art which is not considered to be of particular relevance	* X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
* E earlier document published on or after the international filing date	* Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
* L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	* A document member of the same patent family
* O document referring to an oral disclosure, use, exhibition or other means	
* P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

04 DECEMBER 1996

Date of mailing of the international search report

23 DEC 1996

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3590

Authorized officer

KARIN REICHLE

Telephone No. (703) 308-2617

THIS PAGE BLANK (USPTO)

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER: _____**

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE BLANK (USPTO)